REMARKS

Claims 1 and 5 through 12 are pending in the application.

Applicants acknowledge with gratitude the Examiner's continued indication within the outstanding Office Action at Page 11, last paragraph that contamination of carriers via diffusion is not discussed in the prior art.

Applicants further acknowledge with gratitude the Examiner's indication within the outstanding Office Action at Page 2, penultimate paragraph and Page 6, penultimate paragraph that the specification is enabled for embodiments in which the carrier is polymer and the diffusing contaminant is flavor and/or fragrance.

Applicants likewise acknowledge with gratitude the Examiner's indication within the outstanding Office Action at Page 2, penultimate paragraph that the specification is enabled for embodiments in which the carrier is paper.

Accordingly, Claim 1 has been amended to reflect advantageous embodiments in which polymer has been coated with an active-ingredient-containing coating containing flavor and/or fragrance, and the flavor and/or fragrance contaminating the polymer is subsequently removed via thermal treatment. Support for this amendment can be found in the Application-as-filed.

Claim 1 has further been amended to remove extraneous terminology.

Claim 5 has been amended to reflect advantageous embodiments in which paper has been coated with an aqueous coating containing active ingredients, adjuvants, flavors, or fragrances and active ingredients, adjuvants, flavors, or fragrances contaminating the paper are subsequently removed via thermal treatment. Support for this amendment can be found in the Application-as-filed.

Claim 5 has further been amended to remove extraneous terminology.

Claim 6 has been amended to reflect advantageous embodiments in which polymer has been coated with an active-ingredient-containing coating containing drug-active-ingredients, flavor and/or fragrance, and drug-active-ingredients, flavor and/or fragrance contaminating the polymer is subsequently removed via thermal treatment. Support for Claim 6 can be found in the Application-as-filed, including on Page 4, lines 5 through 12 (drug-active-ingredients).

Claim 6 has further been amended to remove extraneous terminology.

Claim 7 has been amended to conform to Claim 1 as-amended.

Claim 9 has been amended to conform to Claim 5 as-amended.

Claim 10 has been amended to conform to Claim 6 as-amended.

Claims 10 and 11 have been amended to conform to Claim 1 as-amended.

Claim 12 has been amended to reflect advantageous embodiments in which paper or polymer has been coated with an active-ingredient-containing coating containing active-ingredients, adjuvants, flavor and/or fragrance, and active-ingredients, adjuvants, flavor and/or fragrance contaminating the paper or polymer is subsequently removed via thermal treatment. Support for Claim 12 can be found in the Application-as-filed.

Claim 12 has further been amended to remove extraneous terminology.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all

rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Claim Rejections - 35 USC §112

Claims 1 and 5 through 10 stand rejected under 35 U.S.C. 112, first paragraph. The outstanding Office Action at Page 2, penultimate paragraph urges that the specification, while being enabling for paper and polymer carriers, does not reasonably provide enablement for broader carriers and diffusing substances.

The Office Action apparently bases the non-enablement rejection on several references that are cited for the proposition that polymeric films are "impermeable" to drugs, with the Office Action further concluding at Page 4, 4th full sentence that the foregoing references prove that polymers "are not susceptible to diffusion by drug" and hence the claims are not enabled. Applicants respectfully submit that the foregoing assertion is misleading, at best. Applicants respectfully reiterate that in absorption contaminant molecules diffuse into the very outermost regions of a substrate, i.e. near the substrate surface, while "permeation" requires transport of a contaminant through the entire thickness of a polymer film, as illustrated within Willige's Figure 1.7 and as further noted within the outstanding Office Action at Page 8, first partial paragraph.

Absorption is well known within the packaging art. In fact, newly cited Peacock explicitly states that polymers (including polyethylene) are permeable to some degree to most liquids, gases and vapors. (Page 185, last partial paragraph). Hence the Office Action's dismissal of the absorption of drugs into a polymer's surface is improper.

Absorption (i.e. scalping) and permeation, although both dependent on diffusion, are clearly differentiated by the speed with which a given contaminant diffuses into a polymer relative to the product life cycle. In that regard, Peacock states that, although polymers are permeable, it is when the permeability of the polymer is "sufficiently low" that it may be effectively be considered to be "impermeable" on the relevant time scale. (Page 185, last partial

paragraph). Hence Peacock indicates that it is the minimal diffusional speed that causes a particular contaminant to merely be absorbed at the surface of a polymer rather than permeate through the polymer thickness. Stated differently, polymers would be permeable to most liquids, gases and vapors if the permeability test were run indefinitely, based upon the discussion within Peacock.

The outstanding Office Action at Page 5, last partial paragraph cites a number of references as teaching the impermeable nature of various carriers relative to drugs, including Panoz, Theeuwes, Fisher, Berner and Solomon. Applicants respectfully reiterate that the impermeability of the various films within the cited references is irrelevant to their performance in absorbing contaminants.

More specifically, the Office Action cites Theeuwes and Fisher as teaching the "impermeability" of polyethylene relative to drugs. However, Peacock expressly teaches that the "permeability of polyethylene" allows it to slowly release fragrances or medications. (Page 186, first full paragraph). Peacock goes on to note that "scalping" (which is also referred to by those skilled in the art as "absorption" as noted within Willige's Figure 1.7) occurs within polyethylene because the chemical and physical characteristics of molecules allows them to permeate the polyethylene. (Page 187, first partial paragraph). Hence, the cited "impermeability" of polyethylene to drugs discussed within Theeuwes and Fisher refers to inability of polyethylene to transfer drugs through their entire thickness over the testing period (and presumably the product lifetime). Nevertheless, polyethylene (and other polymers) at a minimum suffer from scalping (i.e. absorption) of contaminants, with Peacock further specifically indicating that medications permeate in polyethylene, albeit slowly. Applicants respectfully submit that such it is such scalping (i.e. surface absorption via slow permeation) that gives rise to the contamination of polymers by drug-active-ingredients and the like. Applicants further respectfully submit that such absorption occurs regardless of whether the polymer is generally considered "impermeable" relative to the contaminant, as evidenced by Peacock.

Newly cited Charar similarly evidences the diffusion of contaminants within the outermost surface of polymers, stating that "[o]ne major problem is the absorption of flavor compounds ... into packaging materials." (Page 963, Col. 1, Paragraph 1). Charara merely indicated that several of the terpeneless oil constituents were at a "non-detectable" level based upon the analysis methodology used within his Table 2, but did not state that the compounds were "not absorbed" in contrast to the urgings to the contrary in the outstanding Office Action at Page 8, first partial paragraph. In discussing the results presented within Table 2, Charara instead noted that "[a]bsorption was reduced in the case of HDPE and PP [as] [t]hese highly crystalline polymer were more resistant to diffusion." (Page 965, Col. 1, Paragraph 1). Considered in its entirety, Charara notes that LDPE had the highest absorption values, but that HDPE and PP absorbed flavor constituents as well, albeit to a "lesser extent." (Page 965, Col. 2, Paragraph 2). Thus Charara likewise teaches that absorption occurs within even within highly crystalline polymers.

Accordingly, Applicants respectfully submit that the claims as-amended are fully enabled in light of Peacock and Charara, as well as the remaining art of record.

Particularly, inventive methods in which flavors and/or fragrances from a coating adsorb into polymer and are subsequently removed via thermal treatment, as recited in independent Claim 1 as-amended is sufficiently enabled by the prior art that the invention could be practiced without undue experimentation, as kindly indicated by the Examiner within the outstanding Office Action at Page 12, first full paragraph.

The inventive methods in which active ingredients, adjuvants, flavors, or fragrances from a coating adsorb into paper and are subsequently removed via thermal treatment, as recited in independent Claim 5 as-amended is likewise sufficiently enabled by the prior art that the invention could be practiced without undue experimentation, as kindly indicated by the Examiner within the outstanding Office Action at Page 2, penultimate paragraph.

The inventive methods in which drug-active ingredients, flavors and/or fragrances from a coating adsorb into polymer and are subsequently removed via thermal treatment, as recited in independent Claim 6 as-amended is likewise sufficiently enabled by the prior art that the invention could be practiced without undue experimentation, as kindly indicated by the Examiner within the outstanding Office Action at Page 12, first full paragraph and Peacock's teaching of the slow release of medicament within polymer.

The inventive methods in which flavors, fragrances, adjuvants or drug active-ingredients from a coating absorb into paper or polymer, and are subsequently removed via thermal treatment, as recited in independent Claim 12 as-amended is likewise sufficiently enabled by the prior art that the invention could be practiced without undue experimentation, as kindly indicated by the Examiner within the outstanding Office Action at Page 2, penultimate paragraph in combination with Page 12, first full paragraph; and Peacock's further teaching that polymers are permeable to some degree to most liquids.

Accordingly, Applicants respectfully submit that the claims as-amended clearly comply with the enablement requirement. Applicants thus respectfully request withdrawal of the outstanding rejection.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 and 5 through 12 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such

extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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